## REMARKS

The applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the following remarks.

Claims 1-15, 18-28, 31-38, 41, 42 and 45-51 are pending in this application. Claims 1-15, 18-28, 33-38 41, 42 and 45-51 are withdrawn from further consideration. Claim 31 has been amended. Claims 52-54 have been added. Support for the amended and new claims are throughout the specification and claims as originally filed. No new matter has been introduced by the instant amendments to the claims or by the addition of new claims. Applicants reserve the right to pursue the subject matter cancelled from the instant application in this or a subsequent application.

The Specification stands objected in inadequacy of Abstract, non-descriptiveness of title of the invention, and incorporation of embedded hyperlink.

Claims 31 and 32 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 31 and 32 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement and enablement requirement.

Claims 31 and 32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lanctot et al (U.S.Patent Application Publication, US 2003/0125258).

### Objections to the Specification

Applicant amended the title of the invention to make it clearly indicative of the invention as shown in the amendment above.

Applicant amended the Abstract section to make it concise statement of the technical disclosure of the invention, as shown in the amendment above.

Applicant replaced a paragraph containing embedded hyperlink with a paragraph which contains references in which relevant www server is disclosed. Applicant wishes to note that the references that are referred to in the hyperlinks were available at the time of filing the present patent application, and consequently, the insertion of the actual reference citations do not constitute new matter.

**Rejection under 35 U.S.C. 112, 2nd paragraph**

Claims 31 and 32 stand rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps. Applicant clarify steps to be included in the claimed method as shown above. The invention recited in claim 31 is directed to a screening method for a prophylactic/therapeutic substance for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality. The method comprises (i) bringing a protein comprising an amino acid sequence having an identity of 80% or more to the amino acid sequence starting at Amino Acid No. 1 in the amino acid sequence shown by SEQ ID NO:2 or 4, or a salt thereof, into contact with its receptor in the presence or absence of a test substance, and (ii) selecting the test substance that changes the ability of said protein or salt thereof to bind to said receptor as a candidate for a prophylactic/therapeutic substance for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality. The method clearly contains necessary steps of (i) bringing a protein of interest into contact with its receptor in the presence or absence of a test substance and (ii) selecting the test substance. Support for this amendment can be found, for example, page 74 line 33 to page 77 line 23 of the specification.

Accordingly, withdrawal of the rejection is respectfully requested.

**Rejection under 35 U.S.C. 112, 1st paragraph**

Claims 31 and 32 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement and enablement requirement.

The Office Action stated as follows:

> It is noted by the Examiner that the specification discloses, '[a] partial peptide of SS 169...may be any peptide having eh above-described partial amino acid sequence of SS 169, and having substantially the same quality of activity to that of SS169...the genus of partial peptides used by the claimed methods are not limited with respect to its structure, provided that I has a similar function.
> (page 6, line 4 from the bottom to page 7 line 2 of the Office Action mailed 9/19/2007)
>
> It is also noted by the Examiner that the specification discloses "substantially the same amino acid sequence as the amino acid sequence.....having homology of about 60% or more, preferably about 70% or more, more preferably about 80% or more and particularly preferably about 90% or more, to the amino acid sequence .....the genus of proteins used by the claimed methods are limited to any polypeptide sequence having roughly 60% homology.
> (page 7, lines 3-11)
>
> However, the specification fails to describe any identification of structural characteristics or properties of (1) any protein having ~60% sequence homology to SEE ID NO:2 or 4, (2) any partial peptide, and (3) any salt thereof that can be used in the claimed screening method to serve as a useful tool for the development of prophylactic/therapeutic drugs .....
> Taken together, the genus of "proteins," "partial peptides" or salts thereof' used in the claimed methods encompasses widely variant species, having essentially any stcurture and function.
> (page 7, lines 12-22)

The rejection is respectfully traversed. The claimed method of screening uses a protein comprising an amino acid sequence **having an identity of 80% or more** to the amino acid sequence starting at Amino Acid No. 1 in the amino acid sequence shown by SEQ ID NO:2 or 4, or a salt thereof. The SS169 protein is a relatively small protein consisting of 104 (human) or 101 (mouse) amino acids in its mature form. In addition, conserved amino acid substitutions were well known to one skilled in the art at the filing date of this application. Further, SEQ ID NO.:23 shows more than 80% identity to the amino acid sequence starting at Amino Acid No. 1 in the amino acid sequence shown by SEQ ID NO: 4. Since amino acid sequence of claim 1 is sufficiently characterized by the sequence (SEQ ID NO.:2 or 4) and a member of the

genus is disclosed (SEQ ID.NO.23), claims 31 and 32 satisfy the written description requirement.

As to the enablement requirement, because of the size of the SS169 protein and known conserved amino acid substitution as stated above, claims 31 and 32 are no longer so broad as to encompass a method of using (1) any protein ~60% sequence homology to SE ID NO.: 2 or 4, (2) any partial peptide, and (3) any salt thereof that may be free of said protein or said partial peptide. A skilled artisan could produce an SS169 variant that had a homology of 80% or more to the amino acid sequence of SEQ ID NO:2 or 4 and retained physiological activities of SS169 (e.g., suppression of sugar uptake of a skeletal muscle cell upon insulin stimulation, suppression of glycogen synthesis in a skeletal muscle cell and the like) without undue experimentation based on the description of the specification as well as relatively high identity to the amino acid sequence of SEQ ID NO:2 or 4 and known conserved amino acid substitutions. The resulting SS169 variants are able to serve as a useful tool for the development of prophylactic/ therapeutic drugs for diseases associated with sugar/lipid metabolic abnormalities as described in the specification, for example, page 84 line 9 to page 85, line 20.

Further, claims that encompass a protein having a homology of 80% or more in some applications have been allowed by the U.S. Patent & Trademark Office, e.g., USP 5,756,671 and USP 6,015,692, in spite of lack of working examples of any variants.

Accordingly, the disclosure of a screening method using a protein having amino acid sequence of SEQ ID NO.:2 or 4 commensurate with the breadth of claimed methods encompassing the use of protein comprising an amino acid sequence having an identity of 80% or more to the amino acid sequence starting at Amino Acid No. 1 in the amino acid sequence shown by SEQ ID NO:2 or 4, or a salt thereof.

**Rejection under 35 U.S.C. 102(b)**

Claims 31 and 32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lanctot et al (U.S.Patent Application Publication, US 2003/0125258, herein after Lanctot et al.)

The rejection is respectfully traversed. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 31 is directed to a **screening method** for a prophylactic/ therapeutic substance for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality, which comprises bringing a protein comprising an amino acid sequence having an identity of 80% or more to the amino acid sequence starting at Amino Acid No. 1 in the amino acid sequence shown by SEQ ID NO:2 or 4, or a salt thereof, into contact with its receptor in the presence or absence of a test substance, and selecting the test substance that changes the ability of said protein or salt thereof to bind to said receptor as a candidate for a prophylactic/therapeutic substance for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality.

Lanctot et al. neither taught nor suggest the screening method of the instant invention which comprises the steps of selecting a test substance that changes the ability of SS196 or salt thereof to bind to its receptor as a candidate of a prophylactic/therapeutic agent for a disease involved in differentiation of skeletal muscle cell and/or metabolic abnormality. Further, Lanctot et al. did not disclose that BP-1, which is identical to SS169 of the present invention, is involved in the regulation of differentiation of skeletal muscle cell and/or metabolic abnormality.

Accordingly, teachings of Lanctot et al. does not anticipate the steps of the claimed methods.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Docket No.: 64656 (46590)

Applicants believe no fee is due with this response. However, if a fee is due, please charge the fee to our Deposit Account No. 04-1105.

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Respectfully submitted,

By _____

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